

REMARKS/ARGUMENTS

Claims 17, 20-21, 23, 24, 28 and 33-37 have been amended, based on the Examiner's suggestion. Specifically, these claims have been amended to clarify that the first hyaluronic acid salt and the second hyaluronic acid salt are two separate pre-existing products prior to the step of forming a mixture of these two products. *See page 4, first full paragraph, page 6, second full paragraph, pages 7-8, the bridging paragraph, and page 9, first paragraph, of the Office Action.* As acknowledged by the Examiner, support for the amendments can be found at, e.g., pages 10-14, Examples 1-4 of the originally filed specification. New claims 43-46 are added. Support for these new claims can be found at, for example, page 6, line 14 to page 7, line 12 of the originally filed specification. No new matter is added. Entry of the above amendments is, therefore, respectfully requested. Upon entry of the amendments, claims 17, 20-24, 26-28, 30-31 and 33-46 are pending. Reconsideration of the present application is respectfully requested in view of the above amendments and the following remarks.

Claims 28, 30, 31, 41, and 42 are withdrawn from consideration due to the unity requirement under the pertinent PCT rule. These claims have now been properly identified as "withdrawn." For reasons expressed below, claim 17 is patentable in view of the prior art. Therefore, claims 28, 30, 31, 41, and 42, which all refer to claim 17, share the same inventive concept as claim 17 and meet the unity requirement under the relevant PCT rule. Reconsideration of claims 28, 30, 31, 41, and 42 or rejoinder of these claims is respectfully requested.

Claim Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 17, 20-24, 26-27, and 33-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The Examiner deems that the terms "the first HA salt" and "the second HA salt" recited in independent claim 14 are not clear. In response, Applicants have now amended

the claims to make clear that “the first HA salt” and “the second HA salt” are two separate pre-existing products prior to the step of forming a mixture of these two products, as suggested by the Examiner. Therefore, Applicants respectfully request that the rejections of claims 17, 20-24, 26-27, and 33-40 under 35 U.S.C. § 112, second paragraph be withdrawn.

Claim Rejections under 35 U.S.C. § 102

Claims 17, 20, 23, 24, 26, 27, 33, 37, 38, and 39 stand rejected under 35 U.S.C. 102(b) as being anticipated by Balazas (US 4,582,865).

Claims 17, 20, 23, 24, 26, 27, 33, and 37-40 stand rejected under 35 U.S.C. 102(b) as being anticipated by Malson (US 4,716,514).

As explained in Applicants’ previous response, neither Malson nor Balazas teaches forming a mixture of two pre-existing HA products and cross-linking the mixture. In response, the Examiner comments that the previously presented claims do not make clear that the two HA products are two separate products prior to the step of forming a mixture of the two HA products. As noted above, Applicants have now amended the claims at the Examiner’s suggestion to make clear that the two HA products are two separate products prior to the step of forming a mixture of the two HA products. Therefore, withdrawal of the anticipation rejection of claims 17, 20, 23, 24, 26, 27, 33, 37, 38, and 39 in view of Balazas and the anticipation rejection of claims 17, 20, 23, 24, 26, 27, 33, and 37-40 in view of Malson is respectfully requested.

Claim Rejections under 35 U.S.C. § 102(b) and/or 103

Claims 21, 22, 35, and 36 are rejected under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Malson.

As discussed above and as explained in Applicants’ previous response, nowhere does Malson teach, disclose, or suggest cross-linking a mixture of at least two separate pre-existing

hyaluronic acid salt products as recited in claim 17 of the present application. Therefore, Malson cannot anticipate or render obvious claims 21, 22, 35, and 36, which all depend from claim 17. The Examiner's statement that the claims do not make clear whether the two HA products are two separate pre-existing products prior to the step of forming a mixture becomes moot in view of Applicants' present amendments to the claims. Withdrawal of the rejections of claims 21, 22, 35, and 36 in view of Malson under 35 U.S.C. §102(b) and/or 35 U.S.C. §103(a) is respectfully requested.

Claim Rejections under 35 U.S.C. § 103

Claim 34 is rejected under 35 U.S.C. 103(a) as obvious over Malson. Applicants respectfully traverse.

Claim 34, depending from claim 17, further recites that the mixture contains about 90% by weight of the first hyaluronic acid salt product and about 10% by weight of the second hyaluronic acid salt product, the first hyaluronic acid salt product is a sodium salt having a molecular weight of about 3.10^5 Da, and the second hyaluronic acid salt product is a sodium salt having a molecular weight of about 3.10^6 Da.

First, because claim 34 depends from claim 17 and incorporates all of the limitations of claim 17, the reasons discussed above in connection with rejection of claim 17 in view of Malson is equally applicable to claim 34. Specifically, as noted above, the Examiner's statement that the claims do not make clear that the two HA products are two separate products prior to the step of forming a mixture of the two HA products has become moot in view of Applicants' present amendments to the claims.

Second, as noted above, Malson provides no apparent reason to prompt a person of ordinary skill in the art to form a mixture of two pre-existing HA products. As discussed above,

Malson discloses a gel of only one cross-linked hyaluronic acid product for ophthalmological uses. Without disclosing any benefit of using two pre-existing HA products, a person of ordinary skill in the art would not complicate Malson's process by using two different HA products, which will require at least one additional step (e.g., forming a mixture), at least one additional product (e.g., the second HA product), and thereby lead to a higher cost.

Nor does the Examiner articulate a valid reason that a person of ordinary skill in the art would cross-link two separate pre-existing HA products based on Malson, as required by *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. 398, 82 USPQ2d 1385 (2007). The Examiner argues at pages 11-12, the bridging paragraph, last sentence, "The reason to use HA of different molecular weight is because Malson teaches that it can be done, how to do it, and the utility of the resulting composition." This statement is off the point. As noted above, Malson only discloses the use of ONE cross-linked HA product with one definitive molecular weight at ONE TIME. Although Malson suggests the molecular weight of the one HA product can be varied in another batch or process, it never discloses cross-linking of TWO separate pre-existing HA products each having a different molecular weight (and therefore viscosity) from each other at ONE TIME. Nor does Malson teach, disclose, or suggest whether cross-linking of two separate pre-existing HA products with different molecular weight and viscosity can be done, how to do it, and the benefit of doing so.

Third, nowhere does Malson discloses the use of two pre-existing HA products, with one HA product having a molecular weight of about 3.10^5 Da and being used in the amount of about 90%, and the other HA product having a molecular weight of about 3.10^6 Da and being used in the amount of about 10% in the mixture. The Examiner does not identify any disclosure in Malson teaching any of these features.

Fourth, unexpected results of the present invention further demonstrate the patentability of the invention described in the claims of the present application. *See* MPEP 716.02 ("GREATER THAN EXPECTED RESULTS ARE EVIDENCE OF NONOBVIOUSNESS.") Specifically, the inventor of the present application surprisingly found that cross-linking two different types of polymers satisfies the following specifications for an injectable hydrogel product: (1) monophase; (2) better mechanical properties and remanence than the equivalent products of the prior art; (3) unaffected or even improved injectability that is still possible with conventional injection forces using conventional injection devices. *See*, for examples, paragraph Nos. 0021-0031 of the published specification. None of these results would have been expected by a person of ordinary skill in the art based on the teachings of Malson, which does not even mention anything about an injectable hydrogel product.

Based on the foregoing, the present application has been placed in condition of allowance. Early and favorable consideration is respectfully requested.

It is believed that no fees or charges are required at this time in connection with the present application. However, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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